Attorney Docket No.: 050623.00211

REMARKS

Amendments to the Specification

Applicants have amended paragraphs on pages 5, 6, 7, 15, 17, 19, and 20 of the specification to correct typographical errors. No new matter has been added.

Claim Status

Claims 1 – 4, 6, 8 – 12, 15, and 16 were pending. Claims 1 – 4, 6, 8 – 12, 15, and 16 have been rejected. Claims 1, 4, 6, 8, 9, and 15 have been amended. No new matter has been introduced by these amendments. Claims 5, 7, 13, 14, and 17 – 24 were previously cancelled.

Claims 25 – 30 are new. New claims 29 and 30, which depend from claims 1 and 9 respectively, are supported at least by Table 3 on page 14 of the specification. Claims 25 and 26 are new claims that depend from claim 4, and are the same as previous claims 5 and 7. Claims 27 and 28 are new claims that depend from claim 12, and are the same as previous claims 13 and 14. Prior to their cancellation, claims 5, 7, 13, and 14 had been withdrawn as being drawn to unelected species. Thus, the newly added claims 25 – 28 fall within the elected invention, but do not fall within the elected species. However, newly added claims 25 – 28 are claims for which rejoinder is appropriate, and rejoinder is requested in this amendment.

Claims 1 – 4, 6, 8 – 12, 15, 16, and 25 – 30 will be pending upon entry of this amendment.

Reconsideration is respectfully requested.

Claim Rejections - 35 U.S.C. § 103(a)

The Examiner has rejected claims 1 – 4, 6, 8 – 12, 15, and 16 under 35 U.S.C. § 103(a) as being unpatentable over European Patent Application Publication No. EP 0970 711 A2 (Ethicon).

The Examiner's Contentions

It is the Examiner's position that claims 1 – 4, 6, 8 – 12, 15, and 16 are unpatentable as being obvious in view of Ethicon. According to the Examiner, Ethicon discloses polymer coated stents, and among the polymers used are "vinyl halides, polystyrenes and

polyoxymethylenes . . . ." The Examiner has also stated that Ethicon teaches multiple coatings and the use of anti-inflammatory agents in coatings. Thus, it is the Examiner's view that Ethicon teaches "non-acrylic polymers . . . for use in providing similar coatings, and for the same art recognized purpose of modifying the release rate of the drug to be delivered," and that the broad classes of polymers overlap those disclosed by Applicants. As Applicants best understand the Examiner's rejection, the disclosures in Ethicon of the use of a second "material" in paragraph [0029], specifically a second polymer as part of a polymer blend, and the use of polymers that differ in solubility, renders Applicants' claims obvious as "[t]he change in polymer morphology by temperature would have been expected by the ordinary practitioner," and "[f]urther, the inclusion of a 'material' in the form of a second polymer, to modify the rate of drug release would have been expected to produce similar therapeutic results to that of the device instantly claimed."

The Examiner has stated that the Office does not have a laboratory to determine the melting point of polymers. However, the Examiner has then concluded that "[i]t is applicant's burden to show that the polymers of the instant invention would not have been obvious to one of ordinary skill in the art at the time of invention given the teachings of Ethicon Inc.," and that " . . . those of ordinary skill would have expected similar therapeutic results from the instantly claimed coating given the disclosure by Ethicon Inc."

Applicants' Response

Applicants traverse. Independent claims 1 and 9 as well as those claims that depend from them are not rendered obvious by Ethicon.

Without addressing all of the claim elements, claim 1 includes the element "wherein when the body temperature of a patient in which the device comprising the coating is implanted rises to a temperature above the patient's normal body temperature, the morphology of the coating changes so as to change the release rate of the drug in the coating." Claim 9 includes the element "wherein when the body temperature of a patient in which the device comprising the topcoat is implanted rises to a temperature above the patient's normal body temperature, the morphology of the topcoat changes so as to change the release rate of a drug in a coating under the topcoat."

First, the above claim elements of claims 1 and 9 are not rendered obvious by Ethicon. Ethicon is directed to "a process for coating medical devices." (paragraph [0016]) The coating process uses film-forming polymers which may be biostable or bioabsorable. (paragraph [0021]) Paragraphs [0022] and [0023] provide long lists of polymers that may be used. Ethicon provides that other characteristics of the polymer to be used are a molecular weight high enough such that the polymer is not "waxy or tacky," and "to provide sufficient toughness." (paragraph [0024]) Further, Ethicon discloses that the polymer should have good adhesion to the surface of the device, and "[t]he melting point of the polymer used in the present invention should have a melting temperature above 40°C, preferably above about 45°C, more preferably above 50°C and most preferably above 55°C." (paragraph [0024]) Moreover, "[d]ifferent polymers may also be used for different layers in the stent coating." (paragraph [0028])

With respect to the control of drug release, Ethicon provides some guidance. "[A] top coating can be applied to delay release of the pharmaceutical agent . . . ," "the second layer could contain a different drug to provide for sequential drug delivery," or "[m]ultiple layers of different drugs could be provided by alternating layers of first one polymer then the other." (paragraph [0029]) With respect to choice of polymer, Ethicon provides that "[p]olymer blends may also be used to control the release rate of different agents . . . " (paragraph [0029]), "different monomer ratios within a copolymer, polymer structure or molecular weights may result in different solubilities" (paragraph [0029]), and that hydrophilic polymers may be added to a hydrophobic coating to impact drug release, or *vice versa* (paragraph [0031]). The release of the drug is also impacted by the amount of drug included in the coating. (paragraph [0034]) The coatings may also contain "one or more additives, e.g., nontoxic auxiliary substances such as diluents, carriers, excipients, stabilizers or the like." (paragraph [0031])

Although Ethicon provides some broad guidance regarding parameters that modulate release rate, there is nothing in Ethicon that teaches, suggests, or even hints at a coating designed such that "the morphology of the coating changes so as to change the release rate of the drug in the coating," "wherein when the body temperature of a patient in which the device comprising the coating is implanted rises to a temperature above the patient's normal body temperature." There is no discussion in Ethicon about a change in the release rate in response to an external stimulus. All of the guidance in Ethicon is directed to choosing the materials to establish a given release rate. There is no discussion, suggestion, or even a hint that the release rate from the

coating could change after the stent has been implanted due to a change in the environment of implantation. Thus, the above recited elements of claims 1 and 9 would not have been obvious as there is nothing in Ethicon that would have led one of ordinary skill to have expected that Ethicon discloses coatings that "produce similar therapeutic results to that of the device instantly claimed."

Second, Ethicon teaches away from the claimed invention. As best Applicants are able to understand the Examiner's rejection, the Examiner reasons that because Ethicon indicates that polymer blends could be used to modulate drug release rate, Applicants' specification indicates that the second material could be a polymer, and, presumably, it is possible that some of the polymers listed in Ethicon could have "a melting temperature within the range between about 32 °C and 40 °C," Applicants' claims would have been obvious. However, paragraph [0024] of Ethicon states that the polymers should have "a melting temperature above 40°C." Thus, the fact that the USPTO does not have a laboratory to test the melting temperature is irrelevant. In addition, the Federal Circuit recently reiterated the test for determining whether a reference teaches away from the invention:

> A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994)*; *see KSR, 127 S. Ct. at 1739-40*

In re Icon Health and Fitness, Inc., 496 F.3d 1374, 1381; 83 U.S.P.Q.2D 1746 (Fed. Cir., 2007) (emphasis added). Clearly, Ethicon teaches away from using a material, if the material is a polymer, with a "a melting temperature within the range between about 32 °C and 40 °C."

In summary, for at least the reasons discussed above, Applicants' claims 1 and 9, and the claims that depend from them, are not rendered obvious by the disclosure of Ethicon. Applicants request that the Examiner withdraw the 35 U.S.C. § 103(a) rejection.

Rejoinder

Applicants respectfully submit that the pending claims are in condition for allowance. MPEP § 821.04 recites the following:

> The propriety of a restriction requirement should be reconsidered when all the claims directed to the elected invention are in condition for allowance, and the nonelected invention(s) should be considered for rejoinder. Rejoinder involves withdrawal of a restriction requirement between an allowable elected invention and a nonelected invention and examination of the formerly nonelected invention on the merits.
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> In order to be eligible for rejoinder, a claim to a nonelected invention must depend from or otherwise require all the limitations of an allowable claim.

Claims 25 and 26 depend from claim 4, and claims 27 and 28 depend from claim 12. As noted above, these newly added claims fall within the elected invention, but not within the elected species. However, as indicated in the restriction requirement of September 20, 2006, claims 4 and 12 are generic. Thus, if the Examiner chooses to withdraw newly added claims 25 – 28 as being drawn to non-elected species, Applicants respectfully request that the Examiner rejoin these claims and subsequently examine these claims on the merits.

Conclusion

In light of the foregoing claim amendments and remarks, this application is considered to be in condition for allowance. Applicants respectfully request the allowance of pending claims 1 – 4, 6, 8 – 12, 15, 16, and 25 – 30.

If necessary to ensure a timely response, this paper should be considered as a petition for an Extension of Time sufficient to provide a timely response. The undersigned authorizes the Commissioner to charge any fees that may be required, or credit any overpayment to be made, to the **Squire, Sanders, and Dempsey Deposit Account No. 07-1850**.

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Should the Examiner have any questions regarding this communication, the Examiner is invited to contact the undersigned at the telephone number shown below.

Respectfully submitted,

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